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JAN 29 2008

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Patent Department
PO Box 2000
Rahway, NJ 07065-0907

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,981,576

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,981,576, which claims the animal drug product PREVICOX® (firocoxib) and a method of using PREVICOX® (firocoxib), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 651 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 651 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 26, 2007 (72 Fed. Reg. 14119), would be 907 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,118 \text{ days} - 499 \text{ days}) + 98 \text{ days} \\ &= 907 \text{ days (2.5 years)}\end{aligned}$$

Since the regulatory review period began June 29, 1998, before the patent issued (November 9, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 29, 1998, to and including, November 9, 1999, is 499 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 907 days, would extend the patent from October 9, 2016 to April 4, 2019, which is beyond the 14-year limit (the approval date is July 21, 2004, thus, the 14 year limit is July 21, 2018). The period of extension is thus limited to 651 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the

period of extension is the number of days to extend the term of the patent from its original expiration date, October 9, 2016, to and including July 21, 2018, or 651 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,981,576
Granted:	November 9, 1999
Original Expiration Date ¹ :	October 9, 2016
Applicant:	Michel Belley, et al.
Owner of Record:	Merck Frosst Canada LTD.
Title:	Methylsulfonyl Phenyl-2-(5H)-Furanones as COX-2 Inhibitors
Product Trade Name:	PREVICOX® (firocoxib)
Term Extended:	651 days
Expiration Date of Extension:	July 21, 2018

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
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Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
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5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: PREVICOX® (firocoxib)
FDA Docket No.: 2006E-0034

Attention: Beverly Friedman